

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0502]

Agency Information Collection Activities; Proposed Collection; Comment Request; Study to Measure the Compliance of Prescribers With the Contraindication of the Use of Triptans in Migraine Headache Patients With Vascular Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's burden estimates to distribute an Internet-based questionnaire to measure the compliance of prescribers with the contraindication of the use of triptans in migraine headache patients with vascular disease.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD

20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Study to Measure the Compliance of Prescribers With the Contraindication of the Use of Triptans in Migraine Headache Patients With Vascular Disease

Migraine headaches affect about 20 million Americans. Over the last decade, a category of drugs referred to as triptans, has been shown to be efficacious in treating migraine and has been prescribed to millions. However, triptans are routinely contraindicated in patients with vascular diseases due to associated rare occurrence of myocardial infarction, stroke, and other ischemic events. In view of the wide use of this class of drugs and the potential impact on public health, it would be of great use to better understand the prescribing practices as a result of this contraindication.

FDA plans to use the Internet to recruit triptan-user migraine headache patients to determine whether prescribers follow the labeling recommendation to avoid prescribing this class of drugs to patients with pre-existing cardiovascular, cerebrovascular, or peripheral vascular syndromes or with cardiac risk factors. The study is intended to measure the proportion of patients that were prescribed triptans although they have pre-existing cardiovascular, cerebrovascular, or peripheral vascular syndromes.

Soliciting patients over the Internet will identify a cohort of triptan users. These patients will then be asked to fill out a questionnaire about their medical history with a focus on vascular diseases. Following that, a sample of patients' medical records will be solicited and reviewed to verify the medical history. Prevalence of cardiovascular, cerebrovascular, or peripheral vascular ischemic diseases among migraine patients using triptans will be estimated. Information about patients' demographics, route of administration (oral, injection, intranasal), and duration of exposure to triptans will also be collected.

There are no available estimates about the rates of various vascular diseases and cardiac risk factors among migraine headache patients using

triptans. The current study is considered a pilot study aimed at providing estimates of such rates to be used as a basis for future studies. Although FDA recognizes that the study population obtained through Internet-based recruitment may not reflect the population of triptan users at large, a signal of substantial prescribing to patients with vascular contraindications in this selected population may warrant further action on the sponsor's part to improve risk management. Improvement of risk management may include further study of the problem, a labeling change, educational programs performed by the sponsor, or increased restrictions on prescribing.

FDA estimates that approximately 500 persons will voluntarily complete the questionnaire. The estimated time for completing each questionnaire is approximately 2 hours, resulting in a total burden of 1,000 hours per year.

The burden of this collection of information is estimated as follows:

TABLE 1.—ESTIMATED ONE-TIME REPORTING BURDEN¹

No. of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours per Response	Total Hours
500	1	500	2	1,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information

Dated: November 7, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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